UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 Civil Action No. 01-12257-PBS Subcategory No: 03-10643
THIS DOCUMENT RELATES TO: *City of New York* v. *Abbott Labs., et al.* (S.D.N.Y. No. 04-CV-06054) *County of Suffolk* v. *Abbott Labs., et al.* (E.D.N.Y. No. 03-CV-229) *County of Westchester* v. *Abbott Labs., et al.* (S.D.N.Y. No. 03-CV-6178) *County of Rockland* v. *Abbott Labs., et al.* (S.D.N.Y. No. 03-CV-7055) *County of Dutchess* v. *Abbott Labs., et al*. (S.D.N.Y. No. 05-CV-06458) *County of Putnam* v. *Abbott Labs., et al.* (S.D.N.Y. No. 05-CV-04740) *County of Washington* v. *Abbott Labs., et al.* (N.D.N.Y. No. 05-CV-00408) *County of Rensselaer* v. *Abbott Labs., et al.* (N.D.N.Y. No. 05-CV-00422) *County of Albany* v. *Abbott Labs., et al.* (N.D.N.Y. No. 05-CV-00425)	Judge Patti B. Saris **LEAVE TO FILE GRANTED ON JUNE 19, 2009**

[Caption Continues on Next Page]

FUL DEFENDANTS' JOINT RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION FOR PARTIAL SUMMARY JUDGMENT

County of Warren v. *Abbott Labs., et al.*)
(N.D.N.Y. No. 05-CV-00468))
County of Greene v. *Abbott Labs., et al.*)
(N.D.N.Y. No. 05-CV-00474))
County of Saratoga v. *Abbott Labs., et al.*)
(N.D.N.Y. No. 05-CV-00478))
County of Columbia v. *Abbott Labs., et al.*)
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Essex County v. *Abbott Labs., et al.*)
(N.D.N.Y. No. 05-CV-00878))
County of Chenango v. *Abbott Labs., et al.*)
(N.D.N.Y. No. 05-CV-00354))
County of Broome v. *Abbott Labs., et al.*)
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PRELIMINARY STATEMENT

In its July 30, 2007 Order regarding plaintiffs' FUL claims, this Court framed the issue that it would need to decide on summary judgment: Can plaintiffs prove that "defendants submitted false or inflated *published* prices which, if truthful, would likely have affected the FUL"? *In re Pharm. Indus. Average Wholesale Price Litig.*, 498 F. Supp. 2d 402, 405 (D. Mass 2007) (emphasis in original). Stepping back even further, in initially dismissing plaintiffs' FUL claims, the Court recognized that the FUL claims are different than the AWP-based claims with which it has dealt in this litigation to date because the applicable regulation provides that FULs are to be set by the Centers for Medicare and Medicaid Services ("CMS") on the basis of "published prices," defined to mean the prices appearing in the national "publishing compendia." *In re Pharm. Indus. Average Wholesale Price Litig.*, No. 01-12257-PBS, 2007 WL 1051642, at *16 (D. Mass. Apr. 2, 2007) (citing 42 C.F.R. § 447.332). This focus on CMS is important.

Beginning with the very first line of their brief, plaintiffs frame the issue in almost exactly the same way as the Court did. At the top of page one, plaintiffs write, "In July 2007, the Court directed plaintiffs to demonstrate that defendants submitted false prices that, if truthful, would likely have affected the [Federal Upper Limit]." *See* Pls.' Mem. of Law in Support of Mot. for Partial Summary Judgment, at p. 1 (internal quotation marks omitted) (hereinafter "Pls.' Mem.") [Docket No. 78].[1] Plaintiffs, however, then spend the next twenty-one pages of their memorandum advancing arguments that are entirely irrelevant to the process by which CMS sets FULs. This is understandable. On the undisputed record, the answer to the question that the Court poses – would lower published prices likely have affected the FULs that CMS set – the answer is a resounding "NO."

[1] All "Docket No." references are to entries on Sub-Docket No. 03-10643-PBS.

To divert attention from the dispositive question that the Court poses, plaintiffs construct a series of "red-herring" arguments. Plaintiffs first seek to focus attention on New York Medicaid, even though the New York Department of Health played absolutely no role in setting FULs.[2] Plaintiffs then argue that "government knowledge" is irrelevant to their claims, even though (or perhaps because) CMS defined and received Average Manufacturer Prices ("AMPs") and had access to other information about market pricing when setting FULs. And, finally, plaintiffs essentially assert that they must prevail on every issue of any importance because each is already foreclosed by this Court's decision in the *Commonwealth of Massachusetts* v. *Mylan Laboratories* case. Leaving aside that eight of the thirteen defendants against whom plaintiffs move for summary judgment were not parties to that decision and that the decision is not yet final, the *Mylan* decision deals with an entirely different set of issues not at all related to the dispositive issue in this case – that is, would CMS have set lower FULs if the compendia contained lower published prices.

The reason plaintiffs attempt to side-step this dispositive issue is readily apparent: The undisputed facts preclude a showing that lower published prices "would likely have affected the FUL." As discussed at length below, and in Defendants' Motion for Summary Judgment, the record is overflowing with undisputed – indeed, indisputable – facts supporting this conclusion. Two of these facts, however, merit special attention: (1) FULs were set by CMS (not any particular state Medicaid program), and (2) CMS received AMPs (as defined by CMS) from every drug manufacturer participating in the Medicaid program in every quarter since 1991 on an NDC-by-NDC basis, and the individuals responsible for setting FULs have admitted in discovery in this case that they – personally – had access to this AMP information. This context is

[2] As explained more fully in defendants' summary judgment papers, in any event, the New York Department of Health has long understood the difference between "published prices" and lower transaction prices. For this very reason, it urged CMS not to base FULs on published prices.

important both because it distinguishes the issues presented by the FUL summary judgment motions from those previously presented to this Court – *i.e.*, plaintiffs cannot credibly argue that the relevant actor did not have access to AMPs or should not have the knowledge that logically flows from having AMPs imputed to them – and because the choices that CMS made in setting FULs – *i.e.*, its decisions to disregard lower published prices, deviate from the other regulatory requirements in meaningful ways, and sometimes to decline to set a FUL altogether – take on greater significance in this context of indisputable knowledge about market prices.

Contrary to the written regulation, the process by which FULs are set is both manual and highly discretionary. FULs are almost never set based on the lowest published price available, and are even less frequently changed when lower published prices become available. Almost half the time, an actual published WAC for one of the thirteen FUL defendants' products was lower than the WAC used by CMS to set the FUL.[3] These facts are not open for argument. Moreover, it is now clear on the record before this Court that, in setting FULs, while CMS was seeking to achieve some cost savings for the Medicaid program, it was also trying to ensure adequate access to prescription drugs for all Medicaid beneficiaries. Plaintiffs do not dispute these facts. In light of the knowledge that CMS had and the discretion that it exercised in setting FULs, it is impossible for plaintiffs to prevail on a theory that the availability of ***hypothetical*** lower prices would have resulted in a lower FUL when the ***availability of numerous actual lower published prices did not result in CMS's setting lower FULs***. For this reasons alone, Plaintiffs' Motion for Partial Summary Judgment should be denied, and, in fact, as they request, summary judgment should be entered in defendants' favor as to all claims that were reimbursed (or that should have been reimbursed) by New York Medicaid on the basis of FULs.

[3] The thirteen "FUL Defendants" against whom plaintiffs move for partial summary judgment are listed in footnote three of Plaintiffs' Memorandum of Law. References throughout this brief to "defendants" are intended to be limited to the thirteen FUL defendants.

Plaintiffs' Motion for Partial Summary Judgment fails for at least two other reasons. First, plaintiffs have not shown that any of the thirteen defendants who are the subject of plaintiffs' motion acted with the scienter required to violate New York Social Service Law § 145-b ("§ 145-b"). To prove a violation of § 145-b, plaintiffs must establish that a defendant knew or recklessly failed to discover that CMS believed the "published prices" on which CMS chose to base FULs were some kind of an average of transaction prices. Such a claim is absurd. In addition to the fact that CMS, and even more specifically those individuals who were directly responsible for setting FULs, had access to AMPs, the FUL regulatory history makes plain that CMS clearly understood the difference between the "published prices" appearing in the national pricing compendia and the lower transaction prices that were available in the marketplace. Second, the "but for" prices calculated by plaintiffs' putative expert, Harris Devor, on which plaintiffs base their claims, suffer from two fatal flaws: (1) conceptually, Mr. Devor's "but for" prices are nothing more than idiosyncratic calculations of AMP whereby he substitutes his own judgment for CMS's, and (2) in substituting his judgment for CMS's, Mr. Devor arrives at numbers that are so facially unreliable – WACs that are very often higher (and sometimes much higher) than their corresponding AWPs, AWPs that are less than AMPs, and WACs and AWPs that are frequently negative – that, at a minimum, they cannot provide a valid basis for any claim. For these reasons too, plaintiffs' Motion for Partial Summary Judgment should be denied.

BACKGROUND

The parties actually agree on the most basic facts that preclude Plaintiffs' Motion for Partial Summary Judgment and, instead, entitle defendants to the entry of summary judgment in their favor. Plaintiffs flatly concede that the FUL program has "two primary goals": "to ensure access to prescription drugs while taking advantage of the lower prices that are offered in a competitive generic marketplace." (*See* Pls.' Mem., at p. 4.) Plaintiffs further concede that,

"Given the policy objectives of the FUL program, FULs are ***not automatically set*** once the threshold criteria are satisfied." (*Id.* at p. 5 (emphasis added).) In particular, as plaintiffs also concede, once the CMS FULs computer system calculates a FUL based on the regulatory criteria, CMS "engage[s] in a manual review to ensure availability of the drug and accuracy of pricing information." (*See* Pls.' L.R. 56.1 Stmt. of Undisputed Material Facts Related to Federal Upper Limits ("FULs") and Applicable to All Thirteen FUL Defs., at ¶¶ 9-11 [Docket No. 62].) What plaintiffs then work hard to avoid telling the Court is that, as a part of this "manual review" process, CMS exercises such substantial discretion in setting FULs that plaintiffs cannot possibly hope to prove a § 145-b claim.

A. The Undisputed Record Evidence Shows that CMS Exercises Substantial Discretion in Setting FULs.

Plaintiffs' Statement of "Undisputed" Material Facts omits several critical facts. Discovery in this case shows that CMS exercises such substantial discretion in setting FULs that nearly ***75% of the time*** the FUL that CMS set was not based on the lowest published price available as the regulation prescribes. (*See* L.R. 56.1 Stmt. of Undisputed Material Facts Supporting Defs.' Jt. Mot. for Summary Judgment on Pls.' "FUL Fraud" Claims, at ¶ 7 (hereinafter "Defs.' 56.1 Stmt.") [Docket No. 55].) Worse yet for plaintiffs, CMS was free to change (or eliminate) FULs at any time and, still, in ***94% of cases*** (29 out of 31), CMS chose to disregard at least one lower published price during the time that the FUL remained in effect. (*Id.* at ¶ 8.) If any of those lower published prices had been used, the resulting FUL would have been lower. Indeed, for 25 out of 31 FULs, there was ***always*** a lower published price available that, if CMS had chosen to use it, would have resulted in a lower FUL. (*Id.* at ¶ 9.) Moreover, in nearly half the cases in which Mr. Devor calculates a "but for" WAC, the actual existing published WAC for that NDC was already lower than the price that CMS used to set the FUL. (*Id.* at ¶ 68.)

As set forth more fully in defendants' summary judgment papers, CMS also routinely deviated from the FUL regulatory requirements when establishing FULs in other significant ways. CMS sometimes used an outdated price, the price for a non-"A-rated" (or non–therapeutically equivalent) product, a price obtained from a manufacturer directly (and not published anywhere at all), or a price for a package size that was neither the 100-count nor the most commonly available package size, because doing so produced a FUL that "made sense" in light of the goals that CMS was trying to achieve. (*See* Defs.' 56.1 Stmt., at ¶¶ 26-30.) In light of these facts, plaintiffs cannot show any meaningful causal nexus between the prices published for defendants' products and the FULs that CMS set.

B. CMS Certainly Understood the Difference Between "Published Prices" and Lower Transaction Prices.

Plaintiffs' Motion for Partial Summary Judgment leaves out some other critical facts which preclude summary judgment. The FUL regulatory history makes plain that, at all relevant times, CMS understood the difference between "published prices" and the lower transaction prices available in the marketplace, and intentionally chose to set FULs with reference to the former. For example, CMS warns in the final rulemaking of "extremely high payment levels" resulting from CMS's decision to base FULs on "compendia prices" as opposed to the "actual costs of acquiring" the drugs in the marketplace and encourages states to adopt their own "mini-MAC" programs to further control the cost of multisource and generic drugs. *See* Medicare and Medicaid Programs; Limits on Payments for Drugs, 52 Fed. Reg. 28,648, 28,655 (July 31, 1987). In fact, the regulatory history plainly shows that, in deciding to rely on published prices, CMS willingly accepted – indeed, embraced – the prospect of building a "profit margin" for pharmacists into their ingredient cost reimbursement for generic and multiple source drugs subject to FUL. *Id.* at 28,656.

As the CMS witnesses and the parties all agree, and as is unambiguously reflected in the regulatory history, FULs were never intended to be set at a level that approximated a pharmacist's estimated acquisition cost for a drug. Rather, FULs were intended to be an "aggregate" cap on generic drug reimbursement that achieved some cost savings for the Medicaid program, but still afforded states maximum flexibility to set even lower reimbursement levels for multisource and generic drugs if they chose to do so. *See* 52 Fed. Reg. at 28,650 (describing FULs as an "aggregate limit to State spending (but not as a payment method for individual prescriptions"). In the regulatory history, CMS "expressed the hope that States would recognize the advantage of providing pharmacists with an incentive to participate in the Medicaid program [*i.e.*, by providing a "profit margin" on the ingredient cost for generic drugs] and to stimulate pharmacists to engage in prudent purchasing practices and the substitution of lower cost therapeutically equivalent products," but left open the possibility that states might go further and establish their own mini-MAC programs. *Id.* at 28,650 & 28,655-56. As the CMS witnesses explained, FULs were almost never based on the lowest available published price. This was because CMS wanted to strike an appropriate balance between ensuring adequate access for all Medicaid beneficiaries in all states while at the same time capturing some of the cost savings available as a result of price competition in the marketplace for generic drugs. (*See* Defs.' 56.1 Stmt., at ¶¶ 7-9 & 37-38.)

Indeed, the regulatory history highlights that CMS was even willing to accept that neither the states nor CMS would capture all of the potential cost savings available as a result of generic price competition because of its decision to base FULs on published prices rather than lower transaction prices. *See* 52 Fed. Reg. at 28,656 ("[O]ur policy of using published prices as a basis for determining payment levels may cause wholesalers to invent new ways of offering discounts

. . . . The drawback is that neither State programs nor the Federal Medicaid program will benefit from such reductions in wholesale prices."). Indeed, this explicit acceptance of a willingness to forego some of the cost savings serves to underscore the importance that CMS placed on its other objective – ensuring access.

CMS was especially well-positioned to understand the difference between published prices and transaction prices and to strike the intended balance between savings and access to care because CMS had access to AMP and other information about drug pricing available in the generic marketplace. As set forth more fully in defendants' summary judgment papers, the individuals at CMS most directly responsible for setting FULs had access to quarterly AMP information for each drug at the time the FUL determination was made. (Defs.' 56.1 Stmt., at ¶ 39) (Deposition of Sue Gaston at 528:1 – 528:3 ("Q. Would you have had access to that AMP information? A. Yes.")). CMS also had access to – and made use of – information about market prices from manufacturers, wholesalers, pharmacy providers, and state Medicaid agencies. (Defs.' 56.1 Stmt., at ¶¶ 40-43.) In light of this evidence, there can be no doubt that CMS knew very precisely the difference between published prices and lower transaction prices.

C. The "But For" Prices Calculated by Plaintiffs' Putative Expert Are Facially Unreliable.

Finally, plaintiffs rely on two flawed comparisons intended to show the "falsity" of the published prices for defendants' products.[4] First, plaintiffs compare those published prices –

[4] In addition to the two comparative analyses by their expert, plaintiffs also refer to this Court's adoption of a "30% speed bump" as "clearly instructive on the question of AWP falsity." (Pls.' Mem. at 7 n.11.) The Court's ruling that "spreads" in the range of approximately 30% are not misleading or deceptive, however, was based on the well-understood, industry-standard markups between WAC and AWP ***for brand name drugs***. Manufacturers' pricing and price reporting practices and industry expectations and understandings differ dramatically from the brand-name, single-source context to the generic, multisource context. By definition, the FUL issues arise only in the latter context, and it would be a mistake to assume that a ruling based on practices and expectations in the brand context can be applied here, where all of the drugs at issue are multisource. As Professor Berndt explained, "[t]he relationship between AWP, WAC and actual acquisition prices for generic self-administered drugs is considerably

AWPs and WACs – to CMS-defined average transaction prices – AMPs – and insist that the differences show that the published prices were "false." But the plain language of the regulation, the regulatory history, and CMS's conduct make clear that no participant in the system wanted or expected the published prices used in setting FULs to be equal to the transaction prices reported as AMPs. Second, plaintiffs compare published prices for defendants' products to hypothetical "but for" prices calculated by their putative expert, Harris Devor. The alternative prices on which plaintiffs base their claims, however, are inconsistent with the basic structure of pricing in the pharmaceutical industry as understood by this Court and anyone else familiar with the industry. Plaintiffs offer neither evidence nor argument to establish the reliability of Mr. Devor's "but for" prices, and those prices are so unreliable that even he would not vouch for their utility.

Mr. Devor accepts the relatively basic proposition (with which this Court is undoubtedly familiar) that, in the pharmaceutical industry, AWPs are higher than WACs, and WACs are higher than AMPs. (Defs.' Jt. L.R. 56.1 Response to Pls.' Stmt. of Undisputed Material Facts and Counterstatement of Additional Undisputed Facts, at ¶ 2 (hereinafter "Defs.' 56.1 Response").) (Deposition of Harris Devor ("Devor Dep.") at 163:16 – 164:11, 165:8 – 165:21, 170:16 – 171:13, 471:16 – 473:13.) These relationships follow logically from the various points in the distribution chain to which these various pricing measures are intended to relate. (Defs.' 56.1 Response, at ¶ 2) (Devor Dep. at 163:16 – 164:11.) Nonetheless, in circumstance where Mr. Devor calculates both "but for" AWPs and WACs:

- ***60% of the time, the "but for" AWP that he calculates is <u>less than</u> the "but for" WAC*** that he calculates for the very same drug (indeed, this anomalous result occurs at least once for 92% of the NDCs for which Mr. Devor suggests both "but for" prices);

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more complex . . . than that for single source branded drugs. This complexity and variability has been known for quite some time." Berndt Report ¶ 46.

- ***Over one-third of Mr. Devor's "estimated" AWPs were less than their corresponding AMPs*** reported by the manufacturer for that drug during that quarter (again, this anomalous result occurs at least once for nearly 90% of the NDCs for which Mr. Devor calculates "but for" prices); and

- ***Over 10% of the instances where Mr. Devor calculated "but for" AWPs and WACs, at least one of the two was negative***, suggesting that, at one point or another in the distribution chain, the buyer was being "paid" to take the product – a patently absurd result – or, more likely, that Mr. Devor simply did not know how to properly treat returns, credits, and discounts typically reflected in defendants' sales data and, as a result, his "but for" calculations are unreliable.

(Defs.' 56.1 Response, at ¶¶ 3-5.) (Affidavit of Dr. Sumanth Addanki ("Addanki Aff."), at ¶¶ 9-11.) Apparently attempting to mitigate the impact of these truly anomalous "negative numbers," Mr. Devor invents "proxies" (typically the last positive number that he calculates). (Defs.' 56.1 Response, at ¶ 6.) (Addanki Aff., at ¶ 12.) His approach, however, is neither consistent nor transparent (Addanki Aff., at ¶ 4) (Devor Dep. at 143:1 – 8 ("Q: What was your standard for determining when something was an outlier and that you would use a proxy? A: ... I don't remember having any [standard] so it is hard for me to say my standard . . . ."), and it cannot form the basis for the entry of summary judgment in plaintiffs' favor.[5]

Mr. Devor's analysis is also woefully incomplete. Mr. Devor analyzed only about 13% of the NDCs in the relevant GCNs with published prices during the period at issue. (Defs.' 56.1 Stmt., at ¶ 67.) Nevertheless, in about 46% of the instances for which Mr. Devor did calculate a "but for" WAC, the published WAC – already available in one of the national pricing compendia for that very same NDC – was ***lower than*** the WAC that CMS had chosen to use to set the FUL.

[5] There are additional, manufacturer-specific "anomalies" in Mr. Devor's calculations that make them even more unreliable. For example, for certain of the Warrick products at issue, Mr. Devor's calculations include transactions involving the donation of "free goods" to charities, irrelevant classes of trade, and the subtraction of negative numbers without regard for the negative sign in the underlying data – all of which Mr. Devor admits he does without any basis in the record and without having consulted with anyone from Warrick. (Schering Corporation's, Schering-Plough Corporation's, and Warrick Pharmaceutical Corporation's Response to the Pls.' L.R. 56.1 Stmt. of "Undisputed" Material Facts as to Schering Corporation, Schering-Plough Corporation, and Warrick Pharmaceutical Corporation and Statement of Additional Undisputed Material Facts, at ¶¶ 15-21.)

(*Id.* at ¶ 68.) Given that CMS chose not to base the FUL on the actual lowest published price, there is absolutely no reason to believe that CMS would have based the FUL on the different hypothetical price that Mr. Devor calculates if it had been reported. In this regard, Mr. Devor's "analysis" proves defendants' basic point – that plaintiffs cannot show that, had the national pricing compendia published lower prices for defendants' products, CMS likely would have set lower FULs.

It is entirely unsurprising, then, that even Mr. Devor does not stand by his "but for" numbers. Notably, Mr. Devor is unwilling to say that CMS would have used any of the numbers that he calculates if the national pricing compendia had published them instead of the AWPs and WACs that they in fact published for defendants' products. (*See* Defs.' 56.1 Stmt., at ¶ 65.) Mr. Devor intermittently waffles between calling such an exercise entirely speculative and "beyond the scope" of what he was asked to do. (*Id.* at ¶¶ 65-66.) For this reason alone, the Court should not consider Mr. Devor's "but for" calculations as evidence of anything.

LEGAL STANDARD

Summary judgment is proper only where there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); *Torrech-Hernandez* v. *Gen. Elec. Co.*, 519 F.3d 41, 46 (1st Cir. 2008). The movant's inability to prove an essential element of its claim precludes a granting of summary judgment, *Lopez* v. *Corporacion Azucarera de Puerto Rico*, 938 F.2d 1510, 1516 (1st Cir. 1991), and entitles the opposing party to summary judgment, *Celotex Corp.* v. *Catrett*, 477 U.S. 317, 322 (1986). Although a party may rely on expert testimony when moving for summary judgment, such evidence, like "all other evidence . . . must be reviewed in light of F.R.Civ.P. 56," *Hayes* v. *Douglas Dynamics, Inc.*, 8 F.3d 88, 92 (1st Cir. 1993), and can be rejected if it is not conclusive, *Torres Vargas* v. *Santiago Cummings*, 149 F.3d 29, 35-36 (1st Cir. 1998) ("The party who has

the burden of proof on a dispositive issue cannot attain summary judgment unless the evidence that he provides on that issue is *conclusive*.") (emphasis added).

ARGUMENT

I. PLAINTIFFS CANNOT ESTABLISH A CAUSAL NEXUS BETWEEN THE PUBLISHED PRICES FOR DEFENDANTS' PRODUCTS AND THE FULS THAT CMS ESTABLISHED AS NECESSARY TO PROVE A VIOLATION OF NEW YORK SOCIAL SERVICES LAW § 145-B.

Again, the Court correctly framed the issue to be decided on summary judgment in terms of whether plaintiffs could establish that, had defendants submitted lower prices to the national pricing compendia, those prices "would likely have affected the FUL." *In re Pharm. Indus. Average Wholesale Price Litig.*, 498 F. Supp. 2d at 405. Given that 94% of FULs had lower published prices available either when they were set or while they were in existence, that is clearly not a showing that plaintiffs can make.

A. The Undisputed Record Evidence Precludes a Showing of Any Meaningful Causal Nexus Between the Prices Published by the National Pricing Compendia for Defendants' Products and the FULs that CMS Established.

As discussed above, and at greater length in defendants' summary judgment papers, the undisputed record evidence shows that plaintiffs cannot prove that, had the national pricing compendia published lower prices for defendants' products, those lower prices "would likely have affected the FULs" set by CMS. Looking at the representative drugs selected by both parties for targeted discovery, in nearly ***75% of cases***, CMS chose to disregard lower published prices when setting FULs. (Defs.' 56.1 Stmt., at ¶ 7.) Moreover, even though CMS was free to adjust FULs at any time, in ***94% of cases***, CMS declined to reduce an existing FUL despite the publication by the national pricing compendia of a lower published price. (*Id.* at ¶ 8.) For 25 out of 31 (81%) of the FULs that were the subject of targeted discovery, there was ***always*** a lower published price available during the period in which the FUL remained in effect that, if CMS had

chosen to use it, would have resulted in a lower FUL. (*Id.* at ¶ 9.) In fact, even the work done by plaintiffs' putative expert proves defendants' point. Mr. Devor calculates "but for" WACs that plaintiffs contend would have triggered lower FULs. Tellingly though, in nearly half the cases in which Mr. Devor calculates a "but for" WAC, the actual existing published WAC for that NDC was already lower than the price that CMS used to set the FUL. (*Id.* at ¶ 68.) In light of these facts, plaintiffs cannot prove a § 145-b claim and, in fact, summary judgment should enter in defendants' favor.

B. Given that Plaintiffs Cannot Demonstrate Any Meaningful Causal Nexus Between the Published Prices for Defendants' Products and the FULs that CMS Set, Plaintiffs Cannot Prove a § 145-b Violation.

To establish a violation of New York Social Services Law § 145-b based on the report of allegedly false data to a third party (rather than to the governmental entity responsible for paying the claim), the plaintiff must show that the reported data actually "serves as the basis for [the] claim." *See* N.Y. Soc. Serv. Law § 145-b(1)(a), (b). Section 145-b clearly defines what constitutes a false "statement or representation" for purposes of the section. *See id.* § 145-b(1)(b). In doing so, the statute draws a sharp distinction between claims that are presented ***directly*** to the state, a political subdivision of the state, or an entity performing services under contract to the state, on the one hand, and acknowledgements, certifications, claims, ratifications, and reports of data that are subsequently used in connection with the submission of a claim to obtain public funds, but that are not made directly to the governmental entity paying the claim, on the other hand. *Id.* In the case of latter, the plain language of § 145-b(1)(b) requires a showing that the "acknowledgment, certification, claim, ratification or report of data" that forms the basis for the alleged violation actually "serve[d] as the basis for [the] claim." *Id.*

While § 145-b(1)(a) provides that the claim submitted based on the allegedly false data need not result in the payment of funds to constitute a violation of § 145-b – an "attempt" to

obtain funds will be sufficient to establish a violation – a plaintiff still must show that the allegedly false data "serves as the basis for [the] claim." *Id.* When the alleged violation is premised on a more attenuated report of false data to a third party, § 145-b(1)(a)'s "attempt" language does not excuse a plaintiff from its burden of proving causation. The plaintiff still must show that the allegedly false data "serve[d] as the basis for [the] claim," even if the claim does not ultimately result in the payment of any public funds to the defendant. *Id.* at § 145-b(1)(b).

The legislative history of § 145-b supports this commonsense reading of the statute as requiring plaintiffs to prove causation. When § 145-b was enacted in 1975, it reached only false statements or representations that were made directly to the governmental entity from which public funds were sought. *See* N.Y. Soc. Serv. Law § 145-b (McKinney 1975). As the legislative history explains, § 145-b originally was intended to allow the State to recover three times its "actual damages" resulting from only those providers who "overstat[ed] or falsely stat[ed] figures in cost or rate setting forms used for Medicaid reimbursement." 1975 N.Y. Sess. Laws 1686-87 (McKinney). It was not until 1998 that the New York Legislature expanded the scope of § 145-b to encompass claims premised on allegedly false statements and representations that were not made directly to the government by the provider as part of a claim for payment. *See* N.Y. Soc. Serv. Law § 145-b historical & statutory notes (McKinney 2007).[6] At the same time that the Legislature expanded the statute's reach to cover parties that obtained public funds indirectly, *see* § 145-b(1)(c), and broadened the definition of "statement or representation," *see* § 145-b(1)(b), it imposed an explicit causation requirement for claims based on "report[s] of data" that are not made directly to the government as part of a provider's submitting a claim. *Id.*

[6] In fact, to counsels' knowledge, even since the legislative amendment, there has never been a reported decision in which § 145-b has been extended to a claim involving an allegedly false statement made to a third party (rather than directly to the governmental entity that paid the claim). *See, e.g.*, *New York* v. *Sokol* (*In re Sokol*), 113 F.3d 303 (2d Cir. 1997) (billings submitted by a radiologist); *New York* v. *Lutheran Ctr. for the Aging Inc.*, 957 F. Supp. 393 (E.D.N.Y. 1997) (budgets and bills submitted to Medicaid).

(requiring that the "report of data" actually "serve[] as the basis for a claim or a rate of payment"). In these more attenuated circumstances, liability attaches only upon a showing of causation.

C. Even if the Court Were to Import the Federal False Claims Act's Materiality Standard, Plaintiffs Cannot Prove a Claim.

In an effort to avoid having to meet their burden of proving the existence of a meaningful causal nexus between defendants' allegedly wrongful conduct and the FULs that CMS established, plaintiffs repeatedly urge this Court to replace § 145-b's causation requirement with the federal False Claims Act's materiality standard in applying § 145-b. (*See* Pls.' Mem. at pp. 2-3 & n.6, 11, & 20.) As an initial matter, in light of the plain language of § 145-b, it would be clear legal error for the Court to substitute the federal False Claims Act's materiality standard for the showing of causation required by § 145-b where, as here, the alleged violation is premised on the "report of data" not made directly to the governmental payor but rather to a third party. (*See* Point I.B., *supra*.) Even so, plaintiffs cannot prove a claim under the (wholly inapplicable) federal False Claims Act materiality standard.

The undisputed record evidence precludes a showing that the allegedly false published prices for defendants' products had a "natural tendency" or were "capable of influencing" CMS's actions in setting FULs. *See Massachusetts* v. *Mylan Labs.*, 608 F. Supp. 2d 127, 153 (D. Mass. 2008) (discussing the federal False Claims Act's materiality requirement). The essence of plaintiffs' claim is that CMS unwittingly did not understand pricing in the generic marketplace. Clearly this cannot be the case, when CMS was the entity that defined and received AMP for every one of the NDCs at issue in this case. In fact, the very reason plaintiffs urge the Court to ignore "government knowledge" evidence is that CMS actually knew or could have known the average price in the marketplace, as CMS chose to define it, for every drug at issue.

This is not a case in which the government "bumbled its internal accounting procedures," *see United States* v. *President & Fellows of Harvard Coll.*, 323 F. Supp. 2d 151, 185-86 (D. Mass. 2004) (declining to adopt a materiality standard by which a "defendant could always achieve summary judgment simply by finding one or more instances where the government" made a mistake), or was bound up in a long-term contract that, for all practical purposes, required the government to continue making payments despite false certifications that were required by law, *see United States ex rel. Harrison* v. *Westinghouse Savannah River Co.*, 352 F.3d 908, 916-17 (4th Cir. 2003). Nor is this a case in which the defendants are asking the court to judge the materiality of their allegedly false statements based solely on the government's "reaction" to them. *See President & Fellows of Harvard Coll.*, 323 F. Supp. 2d at 186 (declining to adopt such a rule of law); *see also United States ex rel. A+ Homecare, Inc.* v. *Medshare Mgmt. Group, Inc.*, 400 F.3d 428, 445-46 (6th Cir. 2005) (same).

To the contrary, the undisputed record evidence shows unambiguously that CMS clearly understood the significance of basing FULs on published prices rather than lower transaction prices at the time CMS adopted its methodology for setting FULs. *See generally* 52 Fed. Reg. 28,648. Indeed, CMS affirmatively chose to base FULs on published prices despite knowing that doing so would often build a "profit margin" into the drug ingredient cost component of Medicaid reimbursement. *See id.* at 28,656. In fact, CMS had AMPs and clearly understood the difference between AMPs and published prices. Furthermore, CMS chose repeatedly to disregard lower published prices and to deviate from the FUL regulatory requirements in other meaningful ways when setting FULs so as to ensure adequate access for all Medicaid beneficiaries in all states (Defs.' 56.1 Stmt., at ¶¶ 7-9 & 26-31). CMS's actions were not the result of a mistake or misunderstanding. Rather, as the record shows, CMS set FULs after

careful examination of the available information and exercised discretion to achieve important policy goals. The documentary evidence, which is confirmed by the CMS witnesses who were responsible for setting FULs during the relevant times, shows that CMS had access to lower published prices which it often chose to disregard – to actually "cross-out" – and to set higher FULs based on higher published prices to achieve the goal of ensuring adequate access for all Medicaid beneficiaries in all states. (*See id.* at ¶¶ 26-33, 37-38; *see also* Defs.' Mem. in Support of Their Jt. Mot. for Summary Judgment on Pls.' "FUL Fraud" Claims, at Ex. A.) The undisputed record evidence further shows that this happened with such regularity (Defs.' 56.1 Stmt., at ¶¶ 7-9) that it is impossible to say, as plaintiffs' contend, that hypothetical lower prices would have affected the FUL when actual lower prices did not.

If ever there was a case in which the plaintiffs could not meet their burden of proving materiality under the federal False Claims Act, then this is the case. *See, e.g., United States ex rel. Bennett* v. *Genetics & IVF Inst., Inc.*, No. 98-2119, 1999 WL 978881, at *3 (4th Cir. Oct. 28, 1999) (holding that defendant's claims, even if false, were not material under the "natural tendency" test because "everyone knew" that the defendant was not abiding by the terms of the contract, but "[n]one of them cared because all were satisfied with [defendant's] performance under the contract as it was").[7] If the record in this case is not sufficient to preclude a showing of materiality, then the "natural tendency" test is, in effect, meaningless.

II. PLAINTIFFS HAVE NOT ESTABLISHED OTHER ELEMENTS OF A § 145-B CLAIM.

Plaintiffs' Motion for Partial Summary Judgment should be denied for at least two other, independent reasons.

[7] *See also United States* v. *Southland Mgmt. Corp.*, 326 F.3d 669, 680-81 (5th Cir. 2003) (en banc) (Jones, J., concurring) (citing, as support for a finding of immateriality, evidence that the responsible agency official had never stopped payments on any of the 54 projects that she oversaw despite noncompliance with the standard allegedly violated by defendants).

A. The Undisputed Record Evidence Precludes a Showing of the Requisite Scienter.

There is no dispute among the parties that, to establish a violation of § 145-b, plaintiffs must also show that each defendant "knowingly" made a false statement or misrepresentation in an attempt to obtain public funds. *See* § 145-b(1)(a). Plaintiffs attempt to meet their burden of establishing the requisite scienter by listing a series of unremarkable facts defendants supposedly "knew" and then concluding with the unsupported (and unsupportable) claim that "[p]rior rulings of this Court have confirmed, at minimum, the absence of any genuine issue respecting: knowledge." (*See* Pls.' Mem. at p. 15.)

Presumably, plaintiffs' reference to "[p]rior rulings of this Court" is a reference to the Court's *Mylan* decision, 608 F. Supp. 2d 127, which is cited throughout plaintiffs' memorandum. As an initial matter, eight of the thirteen defendants against whom plaintiffs move for summary judgment were not parties to the *Mylan* case at the time of the Court's decision, so it is hard to see how that decision helps plaintiffs as to those defendants. *See Boguslavsky* v. *Kaplan*, 159 F.3d 715, 720 (2d Cir. 1998) (requiring, among other things, that a party have a "'full and fair opportunity' to litigate the issue" for collateral estoppel to apply).[8] Moreover, the *Mylan* decision is not yet final, so collateral estoppel does not apply to any defendant in that case, *id.* (holding that a "valid and final judgment on the merits" is also necessary for collateral estoppel to attach). Most importantly, however, the Court in *Mylan* did not find that any defendant acted with scienter. Instead, the Court ruled that, because "defendants have produced sworn testimony that they believed WACs to be merely an invoice price and that they used it as such, as well as some evidence that some others understood WAC in the same way," "[t]he issue of defendants'

[8] Defendants Barr, Dey, Ethex, Ivax, Roxane, Sandoz, Teva, and Wyeth were not parties to the *Mylan* case at the time the Court issued its summary judgment decision. *See Mylan Labs.*, 608 F. Supp. 2d at 131 n.1. Accordingly, none of these defendants could have had a "full and fair opportunity to litigate" any issue decided in that opinion, as they were not even parties to it. *See Boguslavsky*, 159 F.3d at 720.

knowledge will have to be resolved drug by drug . . . . [as] there still exists a genuine issue as to scienter." *Mylan Labs.*, 608 F. Supp. 2d at 155. That same testimony that this Court found precluded summary judgment in the *Mylan* case is in the record in this case. (*See, e.g.*, Defs.' 56.1 Response, at ¶ 9; *see generally* individual manufacturers' L.R. 56.1 Responses.)

As it relates to scienter, plaintiffs' reliance on the *Mylan* decision is simply inapposite for other reasons as well. Plaintiffs suggest that the issues being considered by the Court in the *Mylan* case were "identical" to the issues presented here.[9] Of course, that is not so. Nowhere in the *Mylan* decision does the Court ever examine the process by which CMS set FULs or consider whether the publication of lower prices would have had any effect whatsoever on the FULs that CMS actually set. Instead, in *Mylan*, the Court construed the term "WAC," which appeared in a Massachusetts EAC regulation, in the context of that regulation. *Mylan Labs.*, 608 F. Supp. 2d at 143. This is not an issue of any significance in answering the question: would the publication of lower prices likely have affected the FULs set by CMS. In fact, the relevant regulatory scheme plainly shows that EAC is not a concept that is even intended to apply to multisource and generic drug ingredient cost reimbursement. *Compare* 42 C.F.R. § 447.331(a) (2006) (multisource drug reimbursement must not exceed the limits established in accordance with 42 C.F.R. § 447.332), *with id.* § 447.331(b) (reimbursement for brand and other non-multisource drugs may not exceed the lesser of EAC plus a reasonable dispensing fee or the provider's usual and customary charge to the general public). Moreover, the regulatory history highlights that CMS understood the term "published prices" to refer to undiscounted list prices. *See* 52 Fed. Reg. at 28,656 (describing "price competition" that HCFA anticipated "would be carried on in the form of discounts" below the "benchmark price[s]" that it intended to use as the basis for FULs).

[9] *See Boguslavsky*, 159 F.3d at 720 (requiring an identity of issue before collateral estoppel will apply).

To the extent that the *Mylan* decision is relevant at all on the issue of scienter, it serves only to highlight that what matters in assessing false claims act liability is whether the ***defendant*** had a good faith and reasonable belief that the prices it was reporting were not false or fraudulent. *Mylan Labs*., 608 F. Supp. 2d at 154-55. When focused in these terms, the *Mylan* case is of no help to plaintiffs here. Again, it bears repeating that, in *Mylan*, this Court found summary judgment to be precluded by individual issues of scienter. *Id.*

B. On the Basis of the Record Before the Court, Plaintiffs Cannot Establish that Defendants Made Any False Statements.

The *Mylan* decision is equally inapplicable as it relates to plaintiffs' burden to show that the AWPs and/or WACs that defendants submitted to the national pricing compendia were false. *See* § 145-b(1)(a). In *Mylan*, the Court ultimately concluded that "the Commonwealth must address falsity drug-by-drug" and declined to decide the issue of falsity on summary judgment. *Mylan Labs*., 608 F. Supp. 2d at 144. Moreover, as noted above, many of the defendants to this case were not parties to the *Mylan* case at the time of the decision, the *Mylan* case is not yet final, and the issues and statutes involved are materially different than those in this case. *See generally Mylan Labs*., 608 F. Supp. 2d 127. Stripped of their rhetoric then, plaintiffs are left to rely solely on their "expert's analysis."

The undisputed record evidence shows, however, that the "but for" prices that Mr. Devor calculates are so facially unreliable that they cannot provide a basis for proving anything. *See Torres Vargas*, 149 F.3d at 35-36 (summary judgment not appropriate when the evidence is not "conclusive"). It is undisputed that one can expect to observe certain relationships among various pharmaceutical pricing benchmarks in the typical distribution chain – that is to say, AWPs that are greater than WACs, and WACs that are greater than AMPs. (Defs.' 56.1 Response, at ¶¶ 1-2.) (Devor Dep. at 163:16 – 164:11, 165:8 – 165:21, 170:16 – 171:13, 471:16

– 473:13.) Nevertheless, despite this commonly-held understanding, plaintiffs' putative expert calculates "but for" prices that simply make no sense – he calculates WACs that are higher than his "but for" AWPs more than 60% of the time, he calculates "but for" AWPs that are less than their corresponding AMPs more than a third of the time, and he calculates "but for" AWPs and WACs that are negative more than 10% of the time. (Defs.' 56.1 Response, at ¶¶ 3-5.) (Addanki Aff., at ¶¶ 9-11.) Moreover, in place of these negative AWPs and WACs, plaintiffs' putative expert substitutes "proxies" on an *ad hoc* basis for the "but for" AWPs and WACs that he calculates, but that he himself finds unreliable. (Defs.' 56.1 Response, at ¶ 6.) (Addanki Aff., at ¶ 12.) It is these hypothetical AWPs and WACs (and sometimes these proxies) that form the basis for plaintiffs' assertion that the AWPs and/or WACs that defendants supplied to the national pricing compendia were false. On this record, plaintiffs' § 145-b claim must fail.

Moreover, the "truth or falsity" of these prices must be judged in light of CMS's understanding of the term "published price" as it is used in the FUL regulation, *see Mylan Labs.*, 608 F. Supp. 2d at 143-44, not this Court's prior definitions of AWP and WAC, which were derived in entirely different statutory and regulatory contexts. *Id.*; *see also In re Pharm. Indus. Average Wholesale Price Litig.*, 460 F. Supp. 2d 277 (D. Mass. 2006). Because there is no evidence in the record to suggest that CMS, which had AMPs, believed the published prices for defendants' products to be transaction prices, and in fact the regulatory history suggests that CMS anticipated price competition occurring in the form of discounting off the published prices that it chose to use to set FULs, *see* 52 Fed. Reg. 28,656, Plaintiffs' Motion for Partial Summary Judgment must fail on the current record for this reason as well.

CONCLUSION

For the foregoing reasons, defendants respectfully request that the Court deny Plaintiffs' Motion for Partial Summary Judgment and enter summary judgment in their favor on all claims that New York Medicaid reimbursed or should have reimbursed on the basis of a FUL.

Respectfully submitted,

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On Behalf of All FUL Defendants

Dated: June 19, 2009

CERTIFICATE OF SERVICE

I hereby certify that on June 19, 2009, I caused a true and correct copy of the foregoing to be served on all counsel of record by electronic service pursuant to Case Management Order No. 2 entered by the Honorable Patti B. Saris in MDL 1456.

/s/ Kim B. Nemirow
Kim B. Nemirow